

Metallic materials for surgical implants —

Part 9: Specification for high-nitrogen stainless steel

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/18, upon which the following bodies were represented:

- Association of British Health-care Industries
- British Forging Industry Association
- British Industrial Ceramic Manufacturers' Association
- British Institute of Surgical Technologists
- British Investment Casting Trade Association
- British Medical Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association
- Department of Health
- Department of Trade and Industry (Laboratory of the Government Chemist)
- Royal College of Surgeons of England
- Royal Veterinary College
- Scottish Office
- Sterilised Suture Manufacturers' Association
- Surgical Dressings Manufacturers' Association

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

- British Dental Association
- Institute of Sterile Services Management

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 February 1993

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National foreword

This Part of BS 7252 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 5832-9:1992 *Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel*, published by the International Organization for Standardization (ISO) and supersedes BS 7252-9:1990, which is withdrawn.

Requirements for metallic materials for surgical implants were first published in BS 3531-2:1980.

As a result of the development of so many disparate Parts of BS 3531 and because of the anticipated need to implement a number of published and forthcoming ISO standards that would have increased the diversity of BS 3531 still further, it was decided that BS 3531 should be restructured as five distinct standards which would enable the various aspects to be clearly differentiated. BS 3531 itself was limited to standards specific to implants for osteosynthesis and its title changed accordingly. Four new standards were published incorporating Parts of BS 3531 as well as new ISO standards, as follows.

BS 7251, *Orthopaedic joint prostheses*.

BS 7252, *Metallic materials for surgical implants*.

BS 7253, *Non-metallic materials for surgical implants*.

BS 7254, *Orthopaedic implants*.

The publication of BS 7252-9:1990 gave requirements for wrought high-nitrogen stainless steel, superseding composition D of BS 3531-2:1980 and together with Parts 1, 2, 3, 4 and 5 of BS 7252, superseded BS 3531-2:1980, which was withdrawn.

This revision of BS 7252-9 specifies ranges of carbon, nickel and chromium which are slightly narrower, introduces compositional limits on residual elements, raises slightly the thin inclusion limits for sulfides and globular oxides and uses the ISO test methods in place of British Standard methods.

Cross-references

International standard	Corresponding British Standard
ISO 629:1982	BS 6200 <i>Sampling and analysis of iron, steel and other ferrous metals</i> Part 3 <i>Methods of analysis</i> Section 3.18 <i>Determination of manganese</i> Subsection 3.18.2:1985 <i>Steel: spectrophotometric method</i> (Identical)

The Technical Committee has reviewed the provisions of ISO 377-1, ISO 404, ISO 437, ISO 439, ISO 643, ISO 671, ISO 3651-2, ISO 4967, ISO 6982 and ISO 10714 to which normative reference is made in the text and has decided that they are acceptable for use in conjunction with this standard.

Related British Standards to ISO 437, ISO 643 and ISO 3651-2 are BS EN 10036, BS 4490 and BS 5903 respectively. A related British Standard publication to ISO 439 is Handbook 19.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.